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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,695	04/14/2004	Levent Oner	22883	6805

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EXAMINER	
MAHYERA, TRISTAN J	
ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
12/29/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/824,695	ONER ET AL.	
	Examiner	Art Unit	
	TRISTAN J. MAHYERA	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/17/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/10/2008 has been entered.

Status of Claims

Claims 1-10 are pending. Claims 1, 7, 9 and 10 have been amended. Claims 1-10 are examined on the merits.

Information Disclosure Statement

Receipt of the IDS filed 9/21/2008 and the fee paid under 1.17(p) is acknowledged and the documents considered.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(a-d), 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged.

Response to Amendments and Arguments

(A) Applicants amendment to add "uncoated" alginic acid or sodium alginate has distinguished over PATEL et al. (US 6,248,363, see PTO-892). Applicants' further arguments are moot in light of the amendments and new grounds of rejection.

Claim Rejections - 35 USC § 103

The statute under this section can be found in the prior office action.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over USLU (WO 03/043641, see PTO/SB/08) in view of WATANABE et al. (US 2002/0150624, see PTO-892) and in view of BLACK et al. (US 2001/0051636, see PTO-892) and evidenced by TRITTHART et al (US 6,242,002 see PTO-892).

USLU teaches a pharmaceutical formulation administered orally containing alendronate mixed with alginates such as alginic acid or sodium alginate as a powder in granule or microparticle form. See e.g. p6 lines 1-8: instant claims 1 and 10. The alginic acid is used in amounts sufficient to prevent esophageal reflux. See e.g. p2 lines 22-27. The alendronate, in the form of alendronate sodium (pharmaceutical derivative of alendronate monosodium trihydrate see p2 lines18-20) is used to prevent loss of calcium in bones with amounts ranging from 5-40mg/day or 35-70mg/week. See e.g. p3 lines 8-15: instant claim 8. The alginates are uncoated and used in amounts ranging from 1mg to 2000mg. See e.g. p5 lines 1-4: instant claims 1 and 10. A ratio of alginates to alendronate in USLU reads on the percents of alendronate (0.001% to 3%) and alginates (0.001% to 2 %) in the instant, i.e. a 1:1 to 2:3 ratio give the stated

percents: instant claims 7 and 9. Lubricants, glidants, fillers and excipients such as aerosil (colloidal silica) and microcrystalline cellulose are used in the formulation. See e.g. p5 lines 2-6: instant claims 2, 3 and 10. The microcrystalline cellulose is used between 10% and 200% of the alginates or between 10% and 1000% of the alendronate. See e.g. p5 lines3-4 and 23-24.

USLU does not teach the use of coating polymers for alendronate or sweeteners for sachet dosing.

WATANABE teaches pharmaceutical compositions for oral use that use the polymer EUDRAGIT E100 (i.e. poly(butyl methacrylate, (2-dimethyl aminoethyl) methacrylate, methyl methacrylate) in a 1:2:1 ratio) as a coating to improving taste masking, moisture resistance and particularly in the case of bisphosphonates, such as alendronate, improving solubility and adsorption. See e.g. pp[0005], [0016], [0017] and [0028] and Example 1: instant claims 1, 5, 6 and 10. The polymer is soluble at gastric pH juices, which reads on gastric pH of 1-4 and implied from its taste masking properties, insoluble at salivary or esophageal pHs, which reads on pHs of 6-7.5: instant claims 1 and 10. See e.g. p[0016].

BLACK teaches the use of bisphosphonates, such as alendronate in sachets with sweetening agents. See e.g. p[0032], [0110] and [0111]: instant claim 1. Specific sweeteners for use in sachets are evidenced by TRITTHART which teaches sweeteners such as saccharin and sucrose are commonly used in sachets to improve flavor and taste. See e.g. claims 2 and 16: instant claim 10. TRITTHART also teaches that

sachets are useful forms for adapting formulation to be dissolved in water before being taken. See e.g. claim 2.

Claims 1, 7, 9 and 10 contain language directed to the properties of the formulation, specifically in claims 1 and 10 that the "alendronate dissolves in 900 ml 0.l N HCl at the rate of not less than 85% of within 30 minutes at the range of pH 1 - 4, and the dispersion in a glass of 250 ml. water at the degree of 25°C contains no dissolved alendronate at pH 6 - 7.5 or at the most 10% w/v of alendronate dissolved in 3 minutes." and claims 7 and 9 whereby the formulation disperses in a glass of 250 ml water at the degree of 25°C at pH 6 - 7.5. Applicants' composition, as claimed, is the same as the prior art. As claimed, Applicants' composition contains the same components in the same configuration as the prior art. Properties are the same when the structure and composition are the same. Thus, burden shifts to applicant to show unexpected results, by declaration or otherwise. *In re Fitzgerald*, 205 USPQ 594. In the alternative, the claimed properties would have been present once the composition was employed in its intended use. *In re Best*, 195 USPQ 433.

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to make a sachet formulation comprising alendronate microparticles coated with a polymer insoluble at pH 6 - 7.5, such as EUDRAGIT E100 and alginic acid or sodium alginate with sweeteners, as taught by USLU in view of WATANABE in view of BLACK and evidenced by TRITTHART. One of ordinary skill in the art at the time the invention was made would have been motivated to combine these elements into a single composition because of the beneficial effects of improved taste,

moisture resistance and particularly in the case of bisphosphonates, such as alendronate, improved solubility and adsorption for the treatment of bone disorders, as taught by WATANABE and the improved taste with sucrose and saccharin in sachets which allow for easy dispersal in water before administration as taught by BLACK and evidenced by TRITTHART. Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention.

Conclusion

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TRISTAN J. MAHYERA whose telephone number is 571-270-1562. The examiner can normally be reached on Monday through Friday 9am-7pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL P. WOODWARD can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Tristan J Mahyera/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615